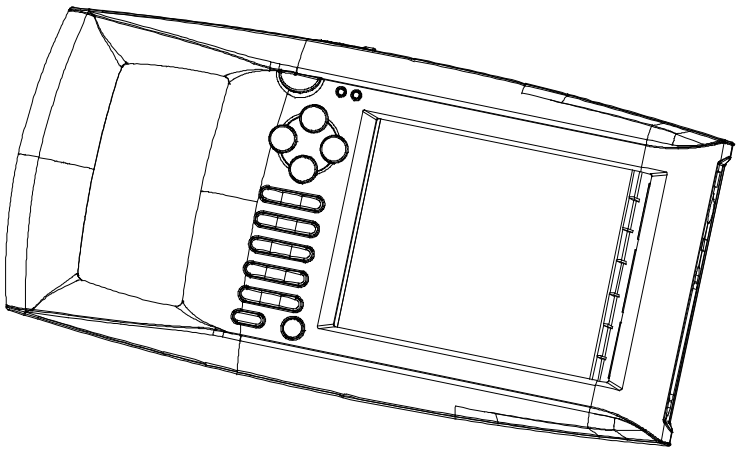
KAIXIN®

KX5100 Ultrasonic Diagnostic Instruments

User's Manual



XUZHOU KAIXIN Electronic Instrument Co., l

Information for Users

Users shall carefully read through this manual and fully understand the text before operating the equipment. This manual shall be placed easy of access for future reference; otherwise it may cause instrument damage or person injury.

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Equipment or units of which the equipment is formed are disassembled and reassemble, extended or readjusted without proper authorization;

Users fail to properly operate the equipment in accordance with the requirements specified in this user's manual.

Product Information

Issue date: June 15, 2011 Version: V1.02

Limited Warranty

Repair Service

1. Kaixin offers Type B lifetime warranty and charge free repair service from the day of purchasing the equipment: eighteen months for main unit and typical configured probe and six months for other components.
2. Within warranty period, the company will not be responsible for the following situation:
   1) Damage or malfunction arising from failing to comply with the instructions of the User's Manual;
   2) Damage or malfunction caused by falling during moving after purchased;
   3) Warranty is expired;
   4) Damage or malfunction due to human factors;
   5) Damage or malfunction caused by disassembling and assembling, alteration and repair without the consent of the company;
   6) Instrument losses induced by Force Majeure (like abnormal power supply, fire, flood, lightning strike, earthquake etc.);
   7) Damage or malfunction caused by use of unqualified ultrasonic coupling gel;
   8) Damage or malfunction caused by use of probe not provided by our company;
3. The company will offer repair service for instrument out of warranty, but additional fees of materials and repair service will be charged.
4. The customer can repair the instrument out of warranty by themselves, and if necessary, the company can provide circuit diagram and components under customers' request.

Return of Goods

Follow the procedure below if you need to return the purchased equipment:

To obtain the right to return the goods, contact local dealer of Kaixin Company, indicating serial number of main unit, this number is located on the nameplate of main unit. Please mark the product model, the serial number of main unit and reason to return the product.

Manufacturer's Information

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Safety Cautions

1. Warning Symbols and Definitions

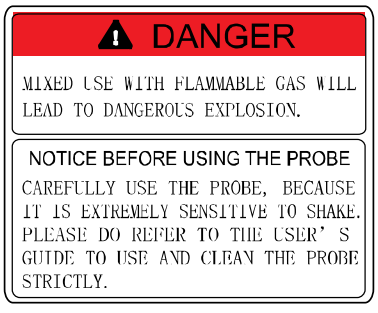
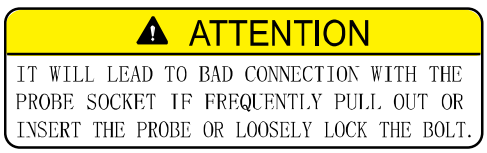
The following warning symbols are used in this manual to indicate safety level and other important items. Please remember these symbols and understand the meaning as you read this user's manual. These symbols convey specific meanings as detailed in the table below:

Symbols & Words	Connotation
⚠Danger	Indicates an imminent danger that may result in personal death or serious injury if not avoided.
⚠Warning	Indicates a potential danger that may result in personal injury if not avoided.
⚠Attention	Indicates a potential danger or unexpected use condition that may result in light injury or property loss or affecting the use if not avoided.
⚠	Indicates that make sure refer to relevant contents in this manual.

2. Safety Symbols

Symbols	Meaning	Symbols	Meaning
	Type B applied part		Up
	AC Power		Keep dry
	DC Power		Fragile
	Power Indicator		Stacking limit by number
	Humidity limitation		Temperature limits
	Atmospheric pressure limitation		Marking for the separate collection of electrical and electronic equipment

3. Labels

Label	Description
	**Danger:** 1. It may have explosion hazard if used with flammable gas. 2. Operate the probe with care. Read the probe information in the relevant manual for proper probe use.
	**Attention:** It is prohibited to pull out a insert the probe frequently.

⚠ ATTENTION ANY NICK OR PRESS TOWARDS THE LCD WILL LEAD TO THE DAMAGE OF THE LCD.	**Attention:** It is prohibited to scratch or squeeze the LCD.
⚠ WARNING The device should be used only with external AC/DC adapter provided by manufacturer,Use of other AC/DC adapter may cause damaged to the device or cause fire and electric shock hazards.	**Warning:** The device should be used only with external AC/DC adapter provided by manufacturer. Use of other AC/DC adapter may cause damaged to the device or cause fire and electric shock hazards.
Lithium Ion Battery Pack KX5100 Rating ⎓ 12.0V 29Wh	Lithium Ion Battery Pack KX5100 Rating: DC 12.0V 29Wh
⚠ Limit To Use With KX5000/ KX5100 Ultrasonic Diagnostic Instrument Only!	Battery pack is limited to use only with KX5000/KX5100 ultrasonic diagnostic instrument.
⚠ ATTENTION 1. DO NOT REMOIST OR THROW THE BATTERY INTO WATER, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 2. DO NOT USE OR STORE THE BATTERY NEAR THE HEAT SOURCE, SUCH AS FIRE OR HEATER, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 3. DO NOT CONNECT THE ANODE AND CATHODE REVERSELY, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 4. DO NOT HEAT UP OR THROW THE BATTERY INTO FIRE, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 5. DO NOT CONNECT THE ANODE AND CATHODE WITH ANY METAL OR LEAD LINE, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 6. DO NOT HAMMERBLOW, THROW OR MECHANICALLY SHAKE THE BATTERY, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 7. DO NOT INSERT THE BATTERY WITH ANY NAIL OR SPICULATE OBJECT, AND DO NOT HAMMERBLOW OR TRAMPLE THE BATTERY, EACH OF WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 8. DO NOT WELD THE PORT OF THE BATTERY DIRECTLY, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 9. DO NOT DISASSEMBLE THE BATTERY IN ANY WAY, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 10. DO NOT CHARGE THE BATTERY NEAR THE HEAT SOURCE OR EXTRA-HOT ENVIRONMENT, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 11. DO NOT PUT THE BATTERY INTO THE MICROWAVE OVEN, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 12. DO NOT MIXEDLY USE THE BATTERY TOGETHER WITH ONE-OFF BATTERY, OR DIFFERENT CAPABILITY OR DIFFERENT MODEL OR DIFFERENT BRAND BATTERY, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 13. DO NOT USE THE ABNORMAL BATTERY WITH PARTICULAR SMELL OR ABNORMAL HEAT OR DISTORTION OR TURN COLORS. 14. DO STOP THE CHARGE AT ONCE IF ANY ABNORMAL PHENOMENON HAPPENS TO THE BATTERY, SUCH AS PARTICULAR SMELL OR ABNORMAL HEAT OR DISTORTION OR TURN COLORS, OTHERWISE, EACH OF ABOVE WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 15. DO REMOVE THE BATTERY FROM THE NEAR FIRE IF ANY LEAKAGE OR PARTICULAR SMELL HAPPENS, WHICH WILL LEAD TO THE LEAKAGE, EXPLOSION OR FIRE. 16. IF ANY LEAKAGE SPLASH INTO EYE, DO NOT WIPE THE EYE, INSTEAD OF WASHING IT AND GET HELP FROM THE DOCTOR AS SOON AS POSSIBLE, OTHERWISE, THE EYE WILL BE INJURED. 17. DO NOT USE THE BATTERY IN THE EXTREMELY HOT ENVIRONMENT, SUCH AS HOT SUNSHINE OR IN THE CAR WHEN IT IS TOO HOT. BECAUSE THESE WILL CAUSE THE FIRE OR SHORTEN ITS LIFE AND WORSEN ITS PERFORMANCE. 18. IF USE THE BATTERY BEYOND THE LISTED ENVIRONMENT ON THE MANUAL, IT WILL CAUSE THE FIRE OR SHORTEN ITS LIFE AND WORSEN ITS PERFORMANCE, EVEN LEAD TO EXTREME HEAT OR EXPLOSION OR FIRE.	**Attention:** Battery use should note the precautions.

	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Ordinances or Regulations for disposal.

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Chapter One Intended Application

KX5100 ultrasonic diagnostic instruments are applicable to abdominal viscera (include trans-vagina, gynecologic and obstetric) and small parts ultrasonic diagnosis.

⚠**Attention: Although ultrasonic diagnostic does not hurt human body, do consider the scanning stop time and frequency for pregnant woman and fetus on the basis of ALARA principle.**

⚠**Attention: The method below should be followed when the intra-cavity probe is used for gynecology and obstetrics.**

1. **Explain the importance and necessity to the subject to get the understanding and coordination.**
2. **Get the bladder calculus, no need to fill the bladder.**
3. **Smear the coupling gel on the top of the probe then put condom on it, and then put the coupling gel on it again. Then place the probe to different position of the uterine cervix and fornix along pelvis axis slowly.**
4. **Use of the rotation, tilt, pumping the basic approaches of pelvic structure sagittal, coronal, traverse and other cross-sectional profile scanning.**
5. **Pay attention to the scanning depth so that the organ of near-filed or the far-filed get into the accumulation area for observing. If the position of organ is higher, the operator can press lower abdomen gently (such as bilanual gynecological examination) by left hand to make it next to probe and get the best showing.**

Chapter Two Technical Specifications

2.1 Technical Parameters

1. Gray Scale: 256
2. Monitor: 6.4" LCD
3. Adapter rating: 100-240V~, 50-60Hz, 70VA (model: MW125RA1203F01)
4. Output of Adapter: DC12V 3.0A
5. Main device rating: DC12V 3.0A
6. Main Unit Dimension: approx. 326×162×47mm^3 (L×W×H)
7. Main Unit Weight: approx 1.5kg (excluding accessories)

2.2 Primary Functions

1. Display Mode: B, B/B, B/M, M, 4B.
2. M Speed: 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s.
3. Magnification: ×0.8, ×1.0, ×1.2, ×1.5, ×1.6, ×2.0, ×2.4, ×3.0.
4. Depth range selection.
5. Depth enhancement/pan function.
6. Local zoom.
7. Adjustment of near field, far field, total gain and dynamic range.
8. Single-point, multi-point focusing.
9. Frequency conversion.
10. Angle/width change.
11. Frame correlation function.
12. Image post-processing.
13. Edge enhancement.
14. Images freeze/unfreeze.
15. Vertical, horizontal flip and B/W conversion.
16. Pseudo color display.
17. Case information, image annotation and auto time display.
18. Body marks.
19. Measurement of distance, depth, circumference, area, volume, slope, heart rate and cycle.
20. OB software package including 15 obstetric tables, automatic calculation of EDC and fetus weight.
21. Puncture guide.
22. Image storage.
23. Cine loop.
24. PAL-NTSC Conversion.
25. Energy saving.
26. Chinese-English Switch.
27. Obstetric report.

Chapter Three Product Outline

3.1 Structure composition of the instrument

KX5100 ultrasonic diagnostic instruments are composed of main unit and probe etc.

3.2 Name of parts and components

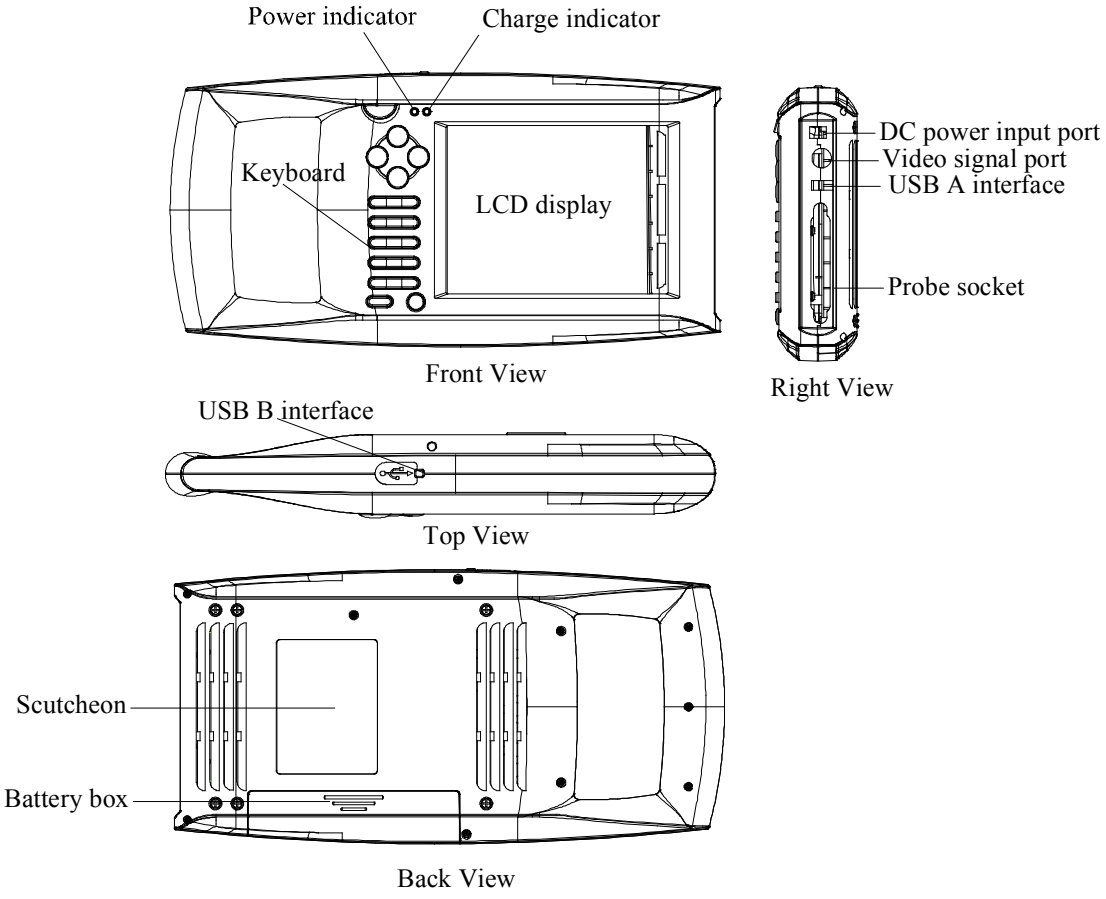


Fig. KX5100 Main Unit sketch map

3.3 Parts of the probe (Take 3.5MHz convex array probe for example)

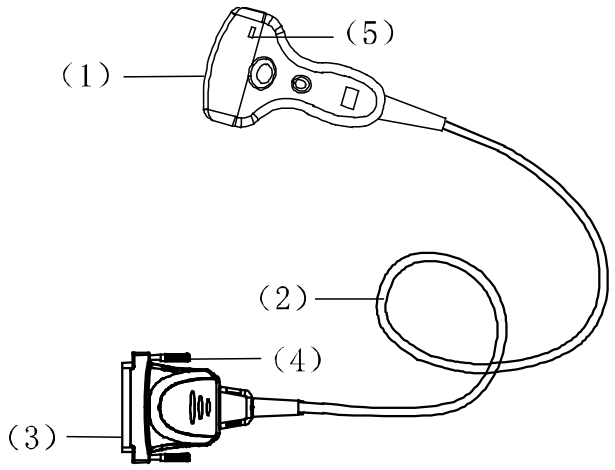


Fig. Name of 3.5MHz convex array probe parts

Name	Function
(1) Acoustic lens	To convert electric signal to ultrasonic signal based on principle of converse piezoelectric effect. The ultrasonic signal, after entering the human body, is reflected as echo wave and converted to electric signal again. The acoustic lens is on the probe surface. Supply ultrasonic coupling gel to the acoustic lens surface when performing ultrasonic diagnosis.
(2) Cable	To connect the probe to probe connector.
(3) Probe connector	To connect the probe to ultrasonic diagnostic system.
(4) Lock / loosen knob	To lock/loosen the connection of probe to ultrasonic diagnostic system.
(5) Fix puncture anchor point	Fix the puncture bracket.

3.4 Function keys description

SN.	Function keys	Real-time mode function	Freeze mode function
1	『Mode/Text』	Mode Selection	Text Input Single image dump
2	『 / 』	Depth enhancement and Depth range selection	Distance/Depth Measurement
3	『 / 』	Local Zoom	Measurement Scaling
4	『 / 』	Puncture Guide	Circumference/Area Measurement Mass images dump
5	『 』	Body Mark	First vice menu quick selection
6	『 』	Obstetrics Measurement	Second vice menu quick selection
7	『 』	Frequency Conversion	Cine loop
8	『Clear』	Clear Screen	
9	『 Enter 』	Enter Confirm menu	
10	『Menu』	Main-menu	
11		Freeze/Unfreeze	
12		Direction keys	
13	Esc	Quit/Fan rotation control	
14	Power	Power switch	

Annotation 1:

1. **First vice menu: Total gain, near field gain, far field gain and dynamic range;**
2. **Second vice menu: Focus selection, frame correlation, post process, edge enhancement and magnification selection**

Annotation 2:

Boot default fan is rotating, in the case of other functions are quitting, press Esc key fan will stop rotating. Fan will work automatically after 25 minutes (stop rotating tim minutes), fan rotating again after 10 minutes before closing the fan.

Chapter Four System Configuration

4.1 Standard Configuration

1. Main unit	1 unit	2. 3.5MHz convex array probe	1 PC
3. Power adapter	1 PC	4. Internal battery	2 PCS

4.2 Optional parts

1. 5.0 MHz micro-convex probe
2. 6.5 MHz intra-cavity probe
3. 7.5 MHz high frequency linear array probe
4. Mouse
5. Video recorder P93W-S

Chapter Five Operation Condition

5.1 Power Supply

Adapter rating: 100-240V~, 50/60Hz, 70VA
Adapter model: MW125RA1203F01
Output of Adapter: DC12V 3.0A
Main device rating: DC12V 3.0A

5.2 Operation Environment

Ambient temperature: 10℃-40℃;
Relative humidity: 30%-75% (without condensation);
Atmospheric pressure: 700hPa-1060hPa.

5.3 Storage and Transport

Ambient temperature: -20℃-55℃;
Relative humidity: 30%-93% (without condensation);
Atmospheric pressure: 700hPa-1060hPa.

⚠**Attention: The mains voltage varies with different countries or regions.**

⚠**Warning: Avoid using this equipment with high frequency operational equipment, or danger may occur.**

⚠**Danger: Do not use this equipment where flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) are present. Failure to do so may result in explosion.**

⚠**Attention: System should be avoided using in following environments:**

1. Splash	**2. No ventilation**
3. Direct sunlight	**4. Dramatic temperature change**
5. Strong shock	**6.Close to heat source**
7. Chemical medicines	**8. Dust**
9. Poisonous gas	**10. Corrosive gas**
11. Rain	**12. Moist**
13. Thunderstorm weather	**14.Strong electromagnetic field (e.g. MRI)**
15. Radiation (e.g., x-ray, CT)	**16.Defibrillators or short wave therapy equipn**

Chapter Six System Installation and Check

⚠Warning:

1. **Do not connect the three-core power supply cord to unprotected two-core socket, or electric shock may occur.**
2. **If breakers and fuse of the mains power socket are identical to those of the this system, and they are used to control the current for equipment like life support system, the system shall not be connected to such power supply socket as it may cause breaker or fuse to trip and cut off the power supply to the entire premise in case of malfunction or over current with this ultrasonic system.**
3. **All plugs of instruments of this system shall be connected into the power socket with protective earth on the wall and the socket must meet the requirement of power rating of instrument. Multiple portable socket-outlets can not be used for the system.**
4. **Equipment that connects the signal input part or signal output part must only connect the accessories authorized in this manual, and connect the equipment that complies with IEC 60601-1 standard. When the instrument connects with more than 3 sets of equipment, it may cause the danger of the leakage current accumulation.**
5. **When this system is installed or used around patient, try to avoid the patient touching the system. If system is with some unknown defects, it may cause danger of electric shock.**

⚠Warning:

1. **When instrument works abnormally, do stop working, turn off the power and check the reason, then contacts the KAIXIN Company about it.**
2. **Turn off power and pull out of the plug from socket after each ultrasonic diagnostic operation.**
3. **It is forbidden to drag and press the power and probe cables emphatically; regularly inspect whether there is pull-apart and bareness, if there is the phenomena like this, turn off power supply immediately and change it for new one.**
4. **It is forbidden to load and unload the probe or move the instrument in galvanic to avoid danger of safety.**
5. **Pull out of the plug from socket after operation in thunderstorm weather to avoid the instrument being damaged by lightening.**
6. **If the temperature changes greatly in short time will cause vapor recovery inside of instrument, the case may damage the instrument.**
7. **The instrument is switched completely only by disconnecting the power supply from the wall socket.**

6.1 System placement

Please carefully read through and fully understand the safety cautions before moving and placing the system.

1. Unpack the instrument case and check the goods for its completeness according to the packing list furnished.
2. Place the base of the machine on a stable and leveled position, and then place the machine or
3. Leave adequate space of 20 centimeters as minimum from rear, left and right side machine.

⚠Attention: Adequate space from rear, left and right side of the machine shall be reserved, or the machine may malfunction under excessive heat inside the enclosure.

6.2 Probe installation

⚠Warning:

1. **The Kaixin ultrasonic probe shall be connected to the dedicated Kaixin ultrasonic system only. Select proper probe model according to the relevant instructions of ultrasonic diagnostic system.**
2. **Check the ultrasonic probe and connecting cable after diagnostic operation. Use of defective probe may cause electric shock.**
3. **Do not knock or bump the probe, or it may be damaged and cause electric shock.**
4. **Unauthorized disassembly of the probe shall be prohibited as it may cause electric shock hazard.**

⚠Attention:

1. **Turn off the ultrasonic system before disconnecting the probe. Disconnecting the probe with system power on may damage the system or probe.**
2. **Before disconnecting the probe, place the cable and probe on a stable and leveled position so that the probe may not be damaged or injury person by unexpected fall.**
3. **Freeze the instrument when instrument is start-up without operation to increase of service life of probe.**
4. **Repeat available machine time should be more than 5 minutes to avoid turn on/off power supply in short time.**

6.2.1 Probe connection

⚠Warning: Make sure that the probe, connecting cable and connector are in normal condition (free of cracks or drop).Use of defective probe may cause electric shock.

1. Insert the probe connector into the probe socket on the right of the main unit. Note the direction of D-head.
2. Rotate the two probe locking knobs clockwise and lock them.

6.2.2 Probe disconnection

First turn off the system, and then rotate the locking knobs counterclockwise, pull out the probe connector vertically.

6.3 Install/dismantle the battery

1. Install battery

   Gently push the battery box into the main unit and then screw the fasten bolts.

2. Dismantle battery

   Remove the fasten bolts as shown in Fig. Clasp the battery box with finger and withdraw it gently.

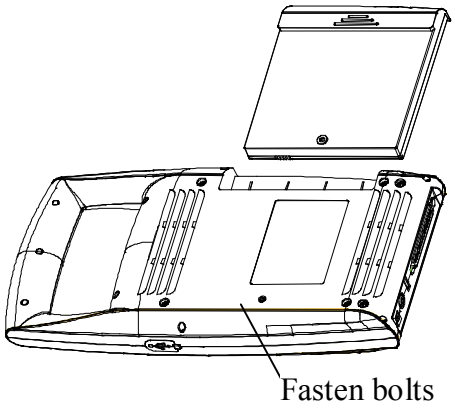


Fig. Install, dismantle the battery

6.4 Connect to video recorder

1. Shutdown the system, connect the equipotential terminal (⏚) of the video recorder to the earthing.
2. Connect the signal connection line to video recorder and the other end to the video output interface on the right of the main unit.
3. Insert the power plug (jack) of the video recorder to its power input socket, the other end to the power supply socket.

6.5 Connect to the mouse

Connect the mouse to USB A interface on the right side of the main unit.

6.6 Connect to the power

1. Connect to the power adapter

Insert the output plug of adapter into DC input socket, which is on the right of main unit.

2. Connect to the main power supply

Insert the power plug (jack) furnished with the machine into power input socket of the power adapter, the other end to the mains socket-outlet. The instrument uses three-core power supply. It connects with the protective earth line when power plug inserts into its socket.

⚠Warning:

1. **Adapter has no switch. The isolation of the system with the MAINS used to unplug the adapter as the intended isolation means.**
2. **The device should be used only with external AC/DC adapter provided by Kaixin Company.**
3. **To avoid damaging power adapter or harming people by unexpected fallen, make sure the power adapter is placed on the leveled desk.**

6.7 Probe check before and after operation

Before and after ultrasonic diagnosis to check if there are any exceptionally on the surface of the probe or cable jacket, such as peeling, cracks, bulge, or if the acoustic lens is reliable, disinfected or cleaned.

6.8 Main unit check before and after operation

6.8.1 Inspection before start-up

Check the following items before starting the machine:

1. The temperature, humidity and atmospheric pressure shall meet the requirements of ope condition.
2. No condensation occurs.

3. No distortion, damage or contamination on system and peripheral. Clean the parts as specified in relevant sections, if the contaminant is present.
4. Check the panel, LCD and enclosure to ensure they are in good working condition and free of abnormity (such as cracks and loosened screws).
5. No damage on power cable, and hard up on its connection.
6. Check probe and its cable to ensure they are free of abnormity (such as scuffing, drop-off or contamination). If the contaminant is present, clean, disinfect the contaminated objects as specified in relevant sections.
7. No barriers around the intake of equipment.
8. See to it that probe has been cleaned, disinfected and sterilized; else dispose it as specified in relevant sections.
9. Check all the ports of the machine for possible damage or blockage.
10. Clean the field and environment.

6.8.2 Inspection after start-up

Check the following items after starting the machine:

1. No abnormal voice, strange smell and overheating appear.
2. Check the machine to ensure a normal start-up: The power indicator is on and startup picture is shown on the screen. The machine will be then automatically set in B mode.
3. Check the ultrasonic lens is abnormal heat or not when the probe is in use. This can be done by hand touching the probe to feel the temperature of the lens.
4. Check image to ensure trouble-free display (no excessive noise or flickering).
5. Check the panel to ensure normal operation condition.
6. Check the instrument to ensure that the phenomenon of high local temperature will not appear.

> ⚠**Attention: If the overheat ultrasonic lens is placed on the patient's skin, heat injury may occur.**

> ⚠**Attention: Thoroughly clean the coupling gel on the probe surface each time after ultrasonic operation, or the coupling gel may become hardened on the acoustic lens of the probe, deteriorating quality of image.**

6.9 System reset

In case of abnormal screen display or system operation, try to restart the system by turning on/off the main unit power.

Chapter Seven Function Operation

7.1 Startup and Shutdown

In shutdown mode, press Power key, machine starts up, power indicator lights.

In startup mode, press Power key, machine shuts down, power indicator goes out. Please note that when shut down the machine, the time of pressing key is a rather long than normal pressing key.

7.2 System Functions Setting

7.2.1 Time Setting

1. Press『Menu』key to enter main-menu and press direction keys to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press direction keys to select "Minutes, Hours, Day, Month and Year";
4. When setting minutes, hours, day, month and year, press direction key to increase value or press direction key to decrease value;
5. Press『Enter』key to confirm the time setting and quit setting interface;

7.2.2 TV Mode Setting

1. Press『Menu』key to enter main-menu and press direction keys to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press direction keys to move symbol "<" to point to "TV mode";
4. Press direction keys to realize TV mode conversion between PAL and NTSC;
5. Press Esc key to quit setting interface.

7.2.3 Energy Saving Setting

1. Press『Menu』key to enter main-menu and press direction keys to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press direction keys to move symbol "<" to point to "Sleep";
4. Press direction keys to select energy saving time or energy saving close between 1~99 minutes;
5. Press Esc key to quit setting interface.

7.2.4 Characters Brightness Setting

1. Press『Menu』key to enter main-menu and press direction keys to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press direction keys to move symbol "<" to point to "Font Bright";
4. Press direction keys to select characters brightness among 160, 192, 224 and 255;
5. Press Esc key to quit setting interface.

7.2.5 Hospital Name Setting

1. Press『Menu』key to enter main-menu and press direction keys to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press direction keys to move symbol "<" to point to "Hospital";
4. Press 『Enter』key, the cursor is located above NAME; at the same time characters inpu will be shown at the bottom of the screen:
   Caps 0 1 2 3 4 5 6 7 8 9 a b c d e f g h

Shift i j k l m n o p q r s t u v w x y z

Press direction keys or operate mouse to move cursor to point to Caps, and then press 『Enter』 key or click left mouse to achieve capital and small letter conversion;

If the cursor point to Shift, press 『Enter』 key or click left mouse again to achieve the conversion between the letter and punctuation;

5. Press direction keys to choose numbers or characters and press『Enter』key to confirm; Or operate mouse to click numbers or characters to input;
6. If need modify the content, press 『Mode/Text』 key to quit the character input menu, press direction keys to delete input content, press 『Mode/Text』 key again to retype;
7. Press Esc key to save this setting and quit setting interface.

7.2.6 Key Sound Setting

1. Press 『Menu』 key to enter main-menu and press direction keys to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press direction keys to move symbol "<" to point to "Key Sound";
4. Press direction keys to select between "On" and "Off";
5. Press Esc key to quit setting interface.

7.2.7 Compression Curve Setting

1. Press 『Menu』 key to enter main-menu and press direction keys to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press direction keys to move symbol "<" to point to "Compression Curve";
4. Press direction keys to select compression curve among "00–07";
5. Press Esc key to quit setting interface.

Note: If use 3.5MHz probe, it is recommended to choose 05 or 06; if use 5.0MHz probe, recommend choose 03 or 04; if use 7.5MHz probe, recommend choose 00 or 01; if use 6.5MHz probe, recommend choose 01 or 02.

7.2.8 Chinese-English Switch

1. Press 『Menu』 key to enter main-menu and press direction keys to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press 『Mode/Text』 key to switch between Chinese and English;
4. Press Esc key to quit setting interface.

7.3 System Formula Setting

1. Press 『Menu』 key to enter main-menu and press key to move cursor to "SETUP";
2. Press direction keys to enter setting interface;
3. Press direction keys to move symbol "<" to point to "Formula Set";
4. Press direction keys to select the desired formula;
5. Press 『 Enter 』 key to confirm this setting and quit the setting interface.

Formula preset table

Preset items	Options
BPD	ASUM China Hadlock Hansmann Jeanty Kurtz Merz Osaka Paris Rempen Shinozuka Tokyo
CRL	ASUM China Hadlock Hansmann Jeanty Nelson Osaka Paris Rempen Robinson Shinozuka Tokyo

Preset items	Options
GS	China Hansmann Hellman Rempen Tokyo
FL	China Hadlock Hansmann Jeanty Merz Osaka Paris Shinozuka Tokyo
HL	Jeanty Merz Osaka
TAD	Eriksen Hansmann Paris
HC	Hadlock Hansmann Jeanty Merz

Preset items	Options
AC	ASUM Hadlock Hansmann Jeanty Merz Shinozuka
FT	Mercer Paris
EFW	Campell German Hadlock1 Hadlock2 Hadlock3 Hadlock4 Hansmann Merz1 Merz2 Osaka Shepard Tokyo

7.4 Mode Selection

In real-time mode, press『Mode/Text』key repeatedly to realize mode switching of B, B/B, 4B, B/M and M.

7.4.1 B Mode

B Mode is the basic operation mode after startup and a single-framed B Mode image is displayed.

7.4.2 B/B Mode

1. In real-time mode, press『Mode/Text』key to enter B/B mode.
2. B/B image switch. Press『Menu』key to enter main-menu and press direction keys to move the cursor to "B/B MODE: " and then press direction keys to switch image display. Or right click mouse to switch image display, the selected image is activated and the other one is frozen.
3. In real-time mode, press『Mode/Text』key to exit B/B mode.

7.4.3 4B Mode

1. In real-time mode, press『Mode/Text』key to enter 4B mode.
2. 4B image switch. Press『Menu』key to enter main-menu and press direction keys to move the cursor to "4B MODE: ", then press direction keys to switch display among four images; Or right click mouse to switch display among four images, the selected image is activated and the other three are frozen.
3. In real-time mode, press『Mode/Text』key to exit 4B mode.

7.4.4 B/M Mode

1. In real-time mode, press『Mode/Text』key to enter B/M mode.
2. Change of scan mode. Press『Menu』key to enter main-menu and press direction keys move cursor to "M DISPLAY: " and then press direction keys to change the M ultr mode. Or right click mouse to realize the change of scan mode.

3. Move sample line. Press direction keys to move sample line.
4. In real-time mode, press『Mode/Text』key to exit B/M mode.

7.4.5 M Mode

1. In real-time mode, press『Mode/Text』key to enter M mode.
2. Change of M-scan mode: Press『Menu』key to enter main-menu and press direction keys to move cursor to "M DISPLAY: " and then press direction keys to change the M ultra-scan mode. Or right click mouse to realize the change of scan mode.
3. Change of M speed: Press『Menu』key to enter main-menu and press direction keys to move cursor to "M SPEED: " and then press direction keys to select the eight kinds of scan speed. Or left click mouse to switch between M speeds.
4. In real-time mode, press『Mode/Text』key to exit M mode.

7.5 Image Quality Adjustment

7.5.1 Brightness and Contrast Adjustment

In the startup default status, press direction keys, the adjustment bars of brightness and contrast will be displayed on the screen, adjust them according to actual need. Press direction key to increase brightness and contrast, direction key to decrease them; press direction keys to select brightness or contrast adjustment.

Note: If direction keys cannot be adjusted when adjust brightness in normal operation mode, must be exit current operating condition of direction keys.

7.5.2 Total Gain Adjustment

In real-time mode, press『Menu』key to enter main-menu and press direction keys to move cursor to "Gain:" in the display area. Press direction key to increase total gain and direction key to reduce total gain so as to control the total gain of the entire image.

7.5.3 Near Field Gain Adjustment

In real-time mode, press『Menu』key to enter main-menu and press direction keys to move cursor to "Near:" in the display area. Press direction key to increase near field gain and direction key to reduce near field gain so as to control the gain in near field region.

7.5.4 Far Field Gain Adjustment

In real-time mode, press『Menu』key to enter main-menu and press direction keys to move cursor to "Far:" in the display area. Press direction key to increase far field gain and direction key to reduce far field gain so as to control the gain in far field region.

7.5.5 Dynamic Range Adjustment

In real-time mode, press『Menu』key to enter main-menu and press direction keys to move cursor to "Dyn:" in the display area. Press direction key to increase the value of dynamic range and direction key to decrease the value of dynamic range so as to control the dynamic range of the entire image.

7.5.6 Quick Adjustment of the image gain and dynamic range

In real-time mode, press『』key repeatedly to enter the first vice menu and switch among the total gain, near filed gain, far field gain and dynamic range. Then press direction keys to adjust the total gain, near filed gain, far field gain and dynamic range.

7.5.7 Frequency Adjustment (Frequency conversion function)

In real-time mode, press『』key to realize frequency conversion. The frequency value is displayed at bottom right of the display.

7.5.8 Focus Adjustment and Control

In real-time mode and in B, B/B or 4B mode, press『Menu』key to enter main-menu an

cursor to "Focus:" and then press direction keys to choose from the four focus modes of stage 1(Full process dynamic focus), 2, 3 and 4.

In real-time mode and in B, B/B, B/M, 4B or M mode, press Esc key to quit menu mode, press direction keys again to move the focus up and down.

Note: In B/M or M mode, only allowed choosing single focus mode.

7.5.9 Frame Correlation Adjustment

In real-time mode, press 『Menu』 key to enter main-menu and press direction keys to move cursor to "FC:" in the display area and then press direction keys to realize the switching of four frames correlation.

7.5.10 Post-process Adjustment

In real-time mode, press 『Menu』 key to enter main-menu and press direction keys to move cursor to "IP" in the display area and then press direction keys to obtain four kinds of corrected image. Four levels of post-process are 0, 1, 2 and 3. System default is 2.

7.5.11 Edge Enhancement Adjustment

In real-time mode, press 『Menu』 key to enter main-menu and press direction keys to move cursor to "IE" in the display area and then press direction keys to gain four kinds of sharpened images. Four levels of edge enhancement are 0, 1, 2 and 3. System default is 0.

7.5.12 Quick Adjustment of Focus, Frame Correlation, Post-process, Edge Enhancement

In real-time mode, press 『』 key repeatedly to enter the second vice menu and switch among the focus, frame correlation, post process, edge enhancement and magnification. Then press direction keys to select the focus mode, frame correlation, post process, edge enhancement and magnification.

7.6 Image Control

7.6.1 Magnification Selection

In real-time mode, press 『Menu』 key to enter main-menu and move cursor to "ZOOM" and then press direction keys to choose eight kinds of magnification.

7.6.2 Depth Enhancement and Depth Range Selection

In real-time mode, press 『/』 key, appears in the center of the screen. Press direction keys or operate mouse to move image up/down or left/right so as to observe the images of different depth and width. Press Esc key to quit depth enhancement/pan status.

Note: Image can not move up and down in the 0.8 magnification.

In real-time mode, press 『/』 key twice, depth selection 1) 17cm 2）18cm 3）19cm 4）20cm 5）21cm 6）22cm 7）23cm 8）24cm are displayed at the bottom of the screen. Press direction keys to select corresponding depth at the bottom of the screen, press 『 Enter 』 key to confirm, press Esc key to quit depth range selection.

Note: There is no depth selection function when main unit matching probe which its nominal frequency greater than or equal to 6.5MHz.

7.6.3 Local Zoom and Local Additive Color

In real time B mode, press 『/』 key, a box appears. Operate direction keys or mouse to move the box to place to be enlarged and the selected image to be enlarged. Press 『/』 key again to quit local zoom status.

In the color display, the selected image which by above mentioned operation will be enlarged and added color.

7.6.4 Image Left/right Flip

In real-time mode and in B, B/B, 4B or B/M mode, press 『Menu』 key to enter main-m
press direction keys to move cursor to "SCAN WAY:" and then press direction keys
realize image horizontal flip. Or left click mouse also to realize image horizontal flip. Th

horizontal flip is the change of probe scanning direction. The probe scanning direction is indicated by the arrow on the upper left area of the image.

7.6.5 Image Up/down Flip

In real-time mode, press 『Menu』 key to enter main-menu and press direction keys to move cursor to "IMAGE: UP" and then press direction keys to realize image vertical flip.

7.6.6 Image Negative

In real-time mode, press 『Menu』 key to enter main-menu and press direction keys to move cursor to "IMAGE: POS" and then press direction keys to realize negative function.

7.6.7 Scan Range (Angle/Width Change)

In real-time mode, press 『Menu』 key to enter main-menu and press direction keys to move cursor to "SCAN ANGL:" and then press direction keys to choose angle/width.(convex array for scanning angle and linear array for scanning width).

7.6.8 Color Conversion

In real-time mode, press 『Menu』 key to enter main-menu and press direction keys to move cursor to "COLOR:" in the display area and then press direction keys to realize color conversion of eight colors (including one kind of black and white).

7.6.9 Image Freeze/Unfreeze

In real-time mode, press freeze/unfreeze key or middle mouse key to freeze the image; in frozen status, press key or middle mouse key to unfreeze the image.

7.7 Puncture guide and lithotripsy positioning line

Puncture guide line: In real-time and B mode, press 『 』 key, two puncture guide lines will be showed on the screen, press direction keys to change the angle of the first puncture guide line, press direction keys to change the start position of the first puncture guide line. Press 『 』 key again to switch the second puncture guide line, press direction keys to change the angle of the second puncture guide line, press direction keys to change the start position of the second puncture guide line. Press Esc key to quit the puncture guide status.

Lithotripsy positioning line: In real-time and B mode, press 『 』 key thrice, lithotripsy positioning line appears on the screen; At the same time, the measurement depth of lithotripsy positioning line "+: 0.0mm" is shown at the top right corner, operate the up/down keys to positioning the depth. Repeatedly press 『 』 key to realize the switch between puncture guide line and lithotripsy positioning line. Press Esc key to quit.

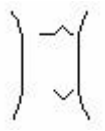
7.8 Body Mark and Probe Mark

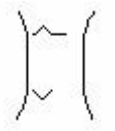
This system contains 64 body marks that are divided into two pages when display, 32 marks for each page. The display operation steps are as follows:

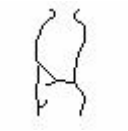
1. In image frozen status, press 『 』 key to show the body marks in display area;
2. Press direction keys to move to the position of desired body mark, press 『Enter』 key to confirm the selected body mark;
3. Press direction keys or operate mouse to change the probe mark position; press 『 』 key to change probe mark direction;
4. Press Esc key to quit body mark and probe mark;
5. Press 『Clear』 key to clear body mark;
6. Press key to unfreeze and quit body mark status.

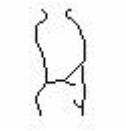
The 64 body marks are listed below:

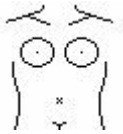
Body Front

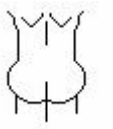

Body Right


Body Left

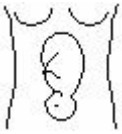

Body Left Lateral

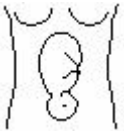

Body Right Lateral


Female Upper Parts


Body Lumbar Rear

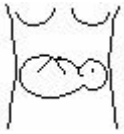
Mother Front

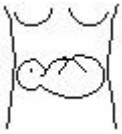

Left Front

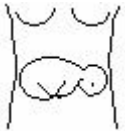

Right Front

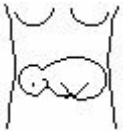
Left Butt Front

Right Butt Front


Left Shoulder Rear

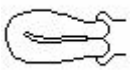

Right Shoulder Rear


Left Shoulder Front

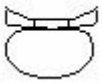

Right Shoulder Front

Uterine Appendages

Uterus Rear


Uterus Level

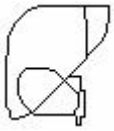
Uterus Front

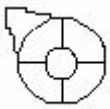

Uterine Body Transection

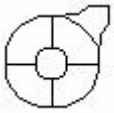
Uterine Neck Transection

Uterine Base Transection

Uterine Transection

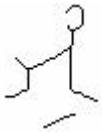

Liver


Breast 1


Breast 2

Neck Front

Neck Right Lateral


Neck Left Lateral

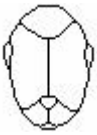
Head Right Lateral

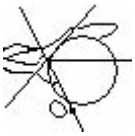
Head Left Lateral

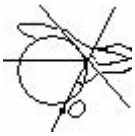
Head Front

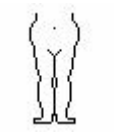
Head Rear

Head Top


Skull Fontanelle Transection


Eyeball 1


Eyeball 2


Lower Limb Front

Lower Limb Rear

Right Arm

Left Arm

Fetus Heart 1

Fetus Heart 2

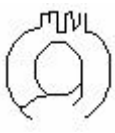
Bilocular Heart

Quad Heart

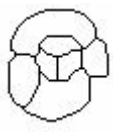
Apical Four Chamber

Apical Five Chamber

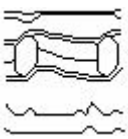
Left Ventricle Major Axis Cross Section


Aortic Arch Major Axis 1

Aortic Arch Major Axis 2


Aorta Minor Axis

Bicuspid valve M-type curve


Aortic valve M-type curve

Large Intestine

St

Thoracic Cavity | Testes | Knee Joint 1 | Knee Joint 2 | Foot 1 | Foot 2 | Hand 1 | Hand 2

7.9 Image storage and recall

7.9.1 Save image

- **Storage to main unit**

1. Freeze the image;
2. Press 『 』 key, a "Save" prompt appears on lower right corner of the screen;
3. Press direction keys to select the image code need to be saved in the "LOCAL", such as choose "003";
4. Press 『Enter』 key to appear "Wait" prompt. After the prompt disappear, the current image is saved in the frame for coded "003". The saved image code is preceded with asterisk "*";
5. Press Esc key to quit saving status and press key to return to real-time status.

- **Storage to U disk**

1. Plug U disk;
2. Freeze the image;
3. Press 『 』 key, a "Save" prompt appears on lower right corner of the screen;
4. Press direction keys to select the image code need to be saved in the U disk, such as choose "004";
5. Press 『Enter』 key to appear "Wait" prompt. After the prompt disappear, the current image is stored in the folder for patient number (ID) as folder name in the U disk, and file name is arranged by the selected saving code that is "4". If user did not enter the number (ID), the folder name defaults to "USER";
6. Press Esc key to quit saving status and press key to return to real-time mode.

Explanation:

1. **Each number (ID) corresponds to a folder, the largest storage for each folder is 100 images.**
2. **Press『Mode/Text』key, can select "LOCAL" or "U Disk".**
3. **If you want to use number (ID) for the folder name, must first input number (ID) and then store image. Folder name is made up of underline, letters or numbers, without spaces.**

7.9.2 Open image

- **Open image stored in the main unit**

1. Freeze the image;
2. Continuously press 『 』 key twice, a "Read" prompt appears on lower right corner of the screen;
3. Press direction keys to select the image code need to be read out in the "LOCAL", such as choose "003*";
4. Press 『 Enter 』 key to appear "Wait" prompt. After the prompt disappear, the image stored in frame "003*" is read out;
5. Press Esc key to quit reading status and press key to return to real-time status.

- **Open image stored in the U disk**

1. Plug U disk;
2. Freeze the image;

3. Continuously press『』key twice, a "Read" prompt appears on lower right corner of the screen;
4. Press direction keys to select the image code need to be read out in the U disk, such as choose "004*";
5. Press『Enter』key to appear "Wait" prompt. After the prompt disappear, the image stored in frame "004*" is read out;
6. Press Esc key to quit reading status and press key to return to real-time status.

Explanation:

1. When reading images, it must choose the image code with "*".

2. If you want to read out the images within the folder identified by number (ID) under the U disk, must input ID first before reading, then do as the above steps; if did not enter the number (ID), it would default to read out the images in the "USER" folder under the U disk.

3. If has read out the images in the U disk, also would like to re-read the local image, must press Esc key to exit this reading status, then press『Mode/Text』key to choose "LOCAL", and vice versa.

7.10 Single dump and mass dump

7.10.1 Single dump

- **From main unit to U disk**

1. Read out the image in the main unit, "Img" with highlight status is displayed on lower right corner of the screen;
2. Press『Mode/Text』key, a "Dump" prompt appears on lower right corner of the screen;
3. Press direction keys to select the image saving code in the U disk, such as choose "005";
4. Press『Enter』key, "Dump" prompt disappears, until the "Dump" re-appears, the current image can be dumped in the frame for coded "005". The dumped image code is preceded with asterisk "*";
5. Press Esc key to quit dumping status and press key to return to real-time status.

- **From U disk to main unit**

1. Enter number (ID), after complete it, and exit input status;
2. Read out the image in the U disk, "Img" with highlight status is displayed on lower right corner of the screen;
3. Press『Mode/Text』key, a "Dump" prompt appears on lower right corner of the screen;
4. Press direction keys to select the image saving code in the "LOCAL", such as choose "006";
5. Press『Enter』key, "Dump" prompt disappears, until the "Dump" re-appears, the current image can be dumped in the frame for coded "006". The dumped image code is preceded with asterisk "*";
6. Press Esc key to quit dumping status and press key to return to real-time status.

Explanation: If not enter number (ID), it will select the image within the system default "USER" folder. The operation steps are 2-6.

7.10.2 Mass dump

- **From main unit to U disk**

1. Freeze the image, continuously press『』key until enter "PAUSE" status;
2. Press『』key, "LOCAL -> U Disk Mass Dump?" prompt display at the bottom of the screen;
3. Press『Enter』key, "Dumping" prompt appears, images are mass dumped under the "I folder in the U disk, and the number behind "PAUSE" character is the number of file ı mass dumping. After finishing mass dumping, return to "PAUSE" status;

4. Press Esc key to quit mass dumping status and press key to return to real-time status.

- **From U disk to main unit**

1. Plug U disk;
2. Freeze the image, continuously press 『』 key until enter "PAUSE" status;
3. Press 『』 key twice, "U Disk -> LOCAL Mass Dump?" prompt display at the bottom of the screen;
4. Press 『Enter』 key, "Dumping" prompt appears, the number behind "PAUSE" character is the number of file name of mass dumping. After finishing mass dumping, return to "PAUSE" status;
5. Press Esc key to quit mass dumping status and press key to return to real-time status.

Explanation:

1. **Mass dump, which is dump images from main unit to "DUMP" folder in the U disk; can also dump the images under the "DUMP" folder in the U disk to main unit.**
2. **If U disk does not have "DUMP" folder, or "DUMP" folder does not have images, or the images within the "DUMP" folder are not named by digital 1-100, press 『Enter』 key, although the screen prompt "Dumping", the image number is not appeared on the right corner of the screen.**

7.11 Delete the image

1. Freeze the image, press 『』 key to enter reading or saving image status;
2. Press 『Mode/Text』 key to switch "LOCAL" and "U disk", identified the location "LOCAL" or "U disk" for file need to be deleted;
3. Press direction keys to select the image code to be deleted, such as "002*";
4. Press 『』 key, the image will be deleted, "*" will automatically disappear;
5. Repeat the 2-3 steps, delete other images;
6. Press key to return to real-time mode.

Explanation:

If you want to delete the images within the folder identified by number (ID) under the U disk, must input ID first before deleting, then do as the above steps; if did not enter the number (ID), it would default to delete the images in the "USER" folder under the U disk.

7.12 Image review

1. Freeze the image, press 『』 key to enter reading or saving image status;
2. Press key to enter the function of "LOCAL" image review, images will be automatically played by the fixed time interval;
3. Press direction keys to select the previous or the next image to review;
4. Press Esc key to return to frozen status.

7.13 Cine loop

In real-time mode, the system is always saving the scanned image. The playback images are for a period time images before freeze.

Freeze the image, press 『』 key three times continuously to enter the automatic playback; Press 『』 key to enter pause status when playing back; Press direction keys or operate mouse to view images frame by frame in pause status; Press 『』 key three times continuously again to return to automatic playback status. In the process of saving and playback, relevant data of image fra saved and played are shown on the lower right corner of the screen.

Press Esc key to return to frozen status.

Press key unfreeze and quit playback status.

Note: If the images appear abnormal, that is without enough storage time and the images have not been stored full.

7.14 Text Input

Operation steps:

1. Freeze image;
2. Press『Mode/Text』key, the cursor is located behind name;
3. Press 『Mode/Text』key again or right click mouse, at the same time characters input menu will be shown at the bottom of the screen:
   Caps 0 1 2 3 4 5 6 7 8 9 a b c d e f g h
   Shift i j k l m n o p q r s t u v w x y z
   Press direction keys or operate mouse to move cursor to point to Caps, and then press 『Enter』key or left click mouse to achieve capital and small letter conversion; If the cursor point to Shift, press『Enter』key or left click mouse again to achieve the conversion between the letter and punctuation;
4. Press direction keys to choose numbers or characters and press『Enter』key to confirm; Or operate mouse to click numbers or characters to input;
5. After inputting name, press『Mode/Text』key and then press direction key to move cursor to serial number and press『Mode/Text』key again to input according to Step 4;
6. After inputting serial number, press『Mode/Text』key and press direction keys to move cursor to image area and press『Mode/Text』key again to input according to Step 4.
7. If need modify the content, press『Clear』key to clear all noted marks and retype;
8. Press Esc key to quit.

Chapter Eight General Measurement

8.1 Distance Measurement

1. In B, B/B or B/M mode, choose desired image and freeze it;
2. Press 『/』 key or click left mouse, the cursor will show "+";
3. Press direction keys or operate the mouse to move the "+" mark to desired position, press 『/』 key or click left mouse to set the "+" mark position as the starting point of the distance to be measured;
4. Press direction keys or operate the mouse to move the"+" mark to the end point of the measured distance. A lighted dotted line appears between the start and the end as the dashed locus of the measurement. The measured value is automatically displayed at the built-in mark"+: ----mm" on the right side of the screen;
5. Press 『/』 key or click left mouse repeatedly to exchange the starting point and end point of the measurement;
6. Press 『/』 key or click right mouse to finish the first measurement;
7. Repeat the steps 3~6 to complete the multi-group data measurement;
8. Press『Clear』key or click the left and right key synchronously to clear all marks and data;
9. Press Esc key to quit the measurement status;
10. Press key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

8.2 Depth Measurement

1. In B, B/B, B/M or M mode, choose desired image and freeze it;
2. Press 『/』 key twice, a dotted line of depth measurement appears on the screen, press direction keys or operate the mouse to move the dotted line to desired position, press direction keys or operate the mouse to move the"+" mark to the end point of the measurement, the measured value of depth is automatically displayed at the built-in mark"+: ----mm" on the right side of the screen;
3. Press 『/』 key or click mouse to complete the multi-group depth measurement;
4. Press 『/』 key to return to the status of distance measurement;
5. Press『Clear』key or click the left and right key synchronously to clear all marks and data;
6. Press key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

Note: Direction keys cannot work in the depth measurement when connecting convex array probe.

8.3 Circumference/Area/Volume Measurement

- **Circumference/area measurement with locus method**

1. In B, B/B mode, choose desired image and freeze it;
2. Press 『/』 key or click left mouse, the cursor will show "+";
3. Press direction keys or operate the mouse to move the "+" mark to desired position, press 『/』 key or click right mouse to set the "+" mark position as the starting point of the measurement;
4. Press direction keys or operate the mouse to move the"+" mark to the end point measurement. At the same time, a locus appears in the direction of operation between measurement marks. The measured circumference value is displayed automatically

built-in mark "C 00000mm" on the right part of the screen. Press 『/』 key or click right mouse to display at the built-in mark "A 00000mm^2" the value of the measured area formed by measurement line enclosure;

5. Repeat steps 3~4 to complete the multi-group data measurement;
6. Press Esc key to quit the measurement status;
7. Press 『Clear』 key or click the left and right key synchronously to clear all marks and data;
8. Press key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

- **Circumference/area/volume measurement with ellipse method**

1. In B, B/B mode, choose desired image and freeze it;
2. Press 『/』 key or click left mouse, the cursor will show "+";
3. Press direction keys or operate the mouse to move the "+" mark to desired position, press 『/』 key or click left mouse to set the "+" mark position as the starting point of the measurement;
4. Press direction keys or operate the mouse to move the"+" mark to the end point of the measurement. Press 『/』 key or click middle mouse, the elliptic curve appears;
5. Press 『Menu』 key until the "−◁ ▷+"mark appears on the screen. Hold down or key to change the minor axis of the ellipse so as to satisfy the test area. The measured values are displayed at the built-in characters "C 00000mm, A 00000mm^2, V 00000cm^3" on the right part of the screen automatically.
6. Press 『/』 key or click left mouse to exchange the starting point and end point. Press 『Menu』 key again to quit status of changing minor axis;
7. Press 『/』 key or click right mouse to finish the first measurement;
8. Repeat the steps from 3 to 7 to complete the multi-group data measurement;
9. Press Esc key to quit the measurement status;
10. Press 『Clear』 key or click the left and right key synchronously to clear all marks and data;
11. Press key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

8.4 Slope/Heart rate/Cycle Measurement

The method to measure slope/hear rate/cycle is identical with distance measurement.

Note: In B/M mode, if both starting point and end point of the measurement mark fall into the B-mode area, the value of the "+: "refers to distance; if starting point and end point of the measurement mark fall into the M-mode area, the value of the "+: "refers to depth; if the starting point and end point are in separate areas, the "+: "will display "----"sign or invalid value.

＋: denotes depth measured in mm (millimeter)
EF: denotes slope coefficient measured in mm/s (millimeter per second)
HR: denotes heart rate measured in times/minute (times per minute)
T: denotes cycle measured in ms (millisecond)

Chapter Nine Obstetric Measurement

9.1 Measurement and Calculation items

BPD (Biparietal Diameter), CRL (Crown Rump Length), GS (Gestational Sac), FL (Femur Length), HL (Humerus Length), LV (Lumbar Vertebrae), TTD (Thorax Transverse Diameter), APTD (Antero-posterior Thorax Diameter), HC (Head Circumference), AC (Abdominal Circumference), FT (Foot Length), TAD (Abdominal Transverse Diameter), THD (Thorax Height Diameter), TCD (Transverse Cerebellum Diameter), OFD (Occipitofrontal Diameter), EFW (Estimated Fetus Weight), EDC (Estimated Date of Confinement), GA (Gestational Age).

9.2 Fetus growth parameter measurement

The following parameters are common evaluation specification of fetus growth. When you measure one of the parameters the system will calculate the GA automatically.

⚠Attention:

1. The measured value of GA is the diagnostic GA.

2. The formulae of every measurement item have been embedded in main unit.

3. Make sure that the measurement is in the effective image area or else it can't calculate right or lead to wrong calculation.

9.2.1 Measurement of GA and EDC

9.2.1.1 Measurement of BPD, CRL, GS, FL, HL, LV, TTD, APTD, FT, TAD, THD, TCD, OFD

Follow the steps below:

1. In B, B/B mode, freeze the desired image;
2. Press 『』 key to display the obstetric parameters on the lower part of the screen;
3. Press direction keys to select corresponding measurement parameters items: BPD, CRL, GS, FL, HL, LV, TTD, APTD, FT, TAD, THD, TCD, OFD; Press 『 Enter 』 key to confirm;
4. Press 『/』 key or click left mouse, the cursor will show "+";
5. Press direction keys or operate the mouse to move the "+" mark to desired position, press 『/』 key or click left mouse to set the "+" mark position as the starting point of the measurement;
6. Press direction keys or operate the mouse to move the"+" mark to the end point of the measurement and GA and EDC value to be displayed in real time in the right area of the screen;
7. Press 『/』 key or click left mouse to exchange the starting point and end point;
8. Press 『/』 key or click right mouse to finish the first measurement;
9. Repeat the steps from 3 to 8 to complete the multi-group data measurement;
10. Press Esc key to quit the measurement status;
11. Press 『Clear』 key or click the left and right key synchronously to clear all marks and data;
12. Press key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

9.2.1.2 Measurement of HC and AC

- **Measuring HC and AC using area method**

Follow the steps below:

1. In B, B/B mode, freeze the desired image;
2. Press 『』 key to display the obstetric parameters on the lower part of the screen;
3. Press direction keys to select measurement parameters in HC, AC, press 『 Enter 』 confirm;
4. Press 『/』 key or click left mouse, the cursor will show "+";

5. Press direction keys or operate the mouse to move the "+" mark to desired position, press 『/』 key or click right mouse to set the "+" mark position as the starting point of the measurement;
6. Press direction keys or operate the mouse, a solid-line measurement locus appear on the screen along the moving direction; circumference, GA and EDC value will be displayed in real time in the right area of the screen; press 『/』 key or click right mouse again to finish the first measurement; in the corresponding right area of the screen display the value (in square millimeter) of the measured area formed by measuring line enclosure;
7. Press Esc key to quit the GA measurement;
8. Press 『Clear』 key or click the left and right key synchronously to clear all marks and data;
9. Press key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

- **Measuring HC and AC using elliptic method**

Follow the steps below:

1. In B, B/B mode, freeze the desired image;
2. Press 『』 key to display the obstetric parameters on the lower part of the screen;
3. Press direction keys to select measurement parameters in HC, AC, press 『 Enter 』 key to confirm;
4. Press 『/』 key or click left mouse, the cursor will show "+";
5. Press direction keys or operate the mouse to move the "+" mark to desired position, press 『/』 key or click left mouse to set the "+" mark position as the starting point of the measurement;
6. Press direction keys or operate the mouse to change the major axis of the ellipse; Press 『Menu』 key the "−◁ ▷+"mark appears on the screen, hold down or key to change the minor axis of the ellipse so as to satisfy the test area, circumference, GA and EDC value will be displayed in real time in the right area of the screen;
7. Press『/』key or click left mouse to exchange the starting point and end point. Press『Menu』 key again to quit the status of changing minor axis;
8. Press 『/』 key or click right mouse to finish the first measurement;
9. Press Esc key to quit the GA measurement;
10. Press 『Clear』 key or click the left and right key synchronously to clear all marks and data;
11. Press key or click the middle mouse to unfreeze, clear all marks and data and quit the measurement status.

9.2.2 Fetus weight measurement

Fetus weight measurement can be done in B, B/B mode. Multi-parameter measurement and storage are required as different formulas are applied to the measurement. These parameter groups for fetus weight measurement include BPD, FTA, FL or BPD, APTD, TTD, FL. Elliptic method shall be used for area and circumference measurement for the fetus weight measurement.

The calculation methods for fetus weight measurement are as follows:

1. In B, B/B mode, freeze the desired image;
2. Press 『』 key to display the obstetric parameters on the lower part of the screen;
3. Press direction keys to select the "16. EFW" parameter;
4. Press『Enter』key to confirm. For example, set the calculation formula of fetus weight to "Osaka", the right area of the screen will appear:

EFW: ---- g
1) ----MM
2) ----MM^2
3) ----MM

At the same time together with relevant parameters "1. BPD, 2.FTA, 3. FL" required for the calculation will be displayed at the bottom of the screen.

In accordance with the order of shown parameters on the bottom of the screen, measure the parameters respectively:

a. Measure BPD with distance measurement method and press 『Enter』 key to confirm. The measured value of BPD is saved and displayed at "1) ----mm" position in the EFW zone of the right display area.

b. ① Press key to exit BPD measurement status;
② Obtain the desired image and freeze it again;
③ Measure FTA with elliptic method of measuring HC, AC and press 『Enter』key to confirm. The measured value of FTA is saved and displayed at "2) ----mm^2" position in the EFW zone of the right display area.

c. ① Press key to exit FTA measurement status;
②Obtain the desired image and freeze it again;
③Measure FL with distance measurement method and press 『Enter』 key to confirm. The measured value of FL is saved and displayed at "3) ----mm" position in the EFW zone of the right display area.

5. When values are available for all the selected parameters, the EFW value is automatically displayed in "EFW: ---- g" position;
6. Press Esc key to quit the measurement status.

⚠Attention: The formulas of fetus weight measurement are all based on estimation. Due to differences in development of individual fetuses and quality of images obtained in different times, the estimated fetus weight may deviate. Therefore, besides using more accurate parameters, it is advisable to measure the fetus weight in various formulae and average the values.

Note: Select other formulas measuring fetus weight. The method and steps are identical with those above.

9.3 Obstetric report

In frozen status, press 『Menu』 key to enter main-menu and press direction keys to move the cursor to the position "REPORT". Press direction keys to display obstetric report. Press direction keys again to exit obstetric report status.

Note:

1. **For measurements done with the given obstetric table, the distance, gestational week and estimated date of confinement are automatically stored in the corresponding places of the obstetric report.**
2. **When performing fetus weight measurement, the system will store the last measurement value only and display the value at the EFW position of the obstetric report.**

9.4 Measurement items

1. Items measurable in B mode: distance, depth, circumference, area, volume, gestational age (GA), estimated date of confinement (EDC) and fetus weight.
2. Items measurable in B/B mode: distance, depth, circumference, area, volume, gestational age (GA), estimated date of confinement (EDC) and fetus weight.
3. Items measurable in B/M mode: distance or depth, slope, heart rate and cycle.
4. Items measurable in M mode: depth, slope, heart rate and cycle.
5. If the display becomes "- - - - -", it indicates an invalid measurement value.

Chapter Ten Principle of Sound Power

10.1 Biological effect

It is generally recognized that ultrasonic diagnosis is safe for human's health. So far, there has been no report on bodily harm done by ultrasound.

Nevertheless it is also believed that not all types of ultrasound are absolutely safe. Relevant researches have already indicated that high-intensity ultrasound is harmful for human body.

With the development of ultrasonic diagnosis technology in recent years, people are more aware of the potential risk in biological effect caused by use of ultrasound and application of ultrasonic diagnostic technology.

10.2 Mechanical effect and thermal effect

Research indicates that two different ultrasonic properties influence human body: one is when ultrasonic subpressure exceed some limited number, air pocket forms mechanical effect; Another is when tissues absorb ultrasonic, appearance of heat energy of ultrasonic may cause thermal effect. Two parameters which are mechanical index MI and heat index TI can explain two types of effects influencing level, the smaller value of MI/TI is, the less bioeffect produce.

10.3 Prudent-use statement

Whereas it is not proved that ultrasonic diagnostic instrument may result in biological effect in human body, there is possibility that such biological effect is proved to be true in the future. Therefore we shall exercise prudence in applying the diagnostic ultrasound to clinical practice. We shall obtain clinical information necessary for the diagnosis with reasonable ultrasound and avoid using high-intensity ultrasound for long period of time.

10.4 ALARA (as low as reasonably achievable) principle

Application of ultrasound shall be based on the ALARA principle that requires a minimized, biological effect-free energy output to obtain necessary diagnostic information. The ultrasonic energy intensity is related to output power and exposure time. Different patients and cases require different ultrasonic intensity.

Not all diagnosis can be done with extra-low ultrasonic energy output. The extra-low ultrasound power produces poor-quality image or weaker Doppler signal that may reduce the diagnostic reliability. On the other hand, use of sound power larger than diagnostically required makes no more contribution to improvement of the diagnostic information quality and increase the risk of biological effect possibility.

Therefore, user of the diagnostic ultrasound shall be fully aware of the patient's safety and choose a proper output level for a specific purpose based on ALARA principle.

10.5 Image control impact on sound power output

Change of image control settings may have influence on sound power output. See table below:

Operation	Consequential impact on sound power output
Change probe	The maximum sound power for each probe has been optimized to FDA standard in order to obtain the best image quality. Therefore the sound power varies with the probe change.
Change image mode	Different parameters are used for B mode and M mode. Therefore change of mode may lead to the change of sound power. If the mode is switched from B to B/B, or to 4B, the sound power will not change as the basic parameters remain the same. In most cases, sound power output in M mode is larger than that in B mode.
Image sight (scanning angle or width)	Change of scanning angle or width may cause the change of frequency, hence the change of sound power.

Number of focus	The number of focus influences frame frequency and focus location, thereby changes the sound power output.
Focus location	Change of transmission focus location leads to change of transmission level and aperture, thereby the change of sound power output.
Freeze	Freeze function initiation disables the system elements transmitting electric energy; therefore the system is not able to transmit the ultrasound.
Transmission power	Change of transmission power will cause the change of system electric output to the probe, hence the change of sound power output.
Change frequency	Change of frequency will lead to the change of wave focus characteristic, thereby the change of sound power output.
Restart or turn off/on	Restart or turn off/on the power will set the system in default mode and change the sound power output.

Chapter Eleven System Clean and Troubleshooting

The system maintenance should be performed by the user and service engineer. Users shall be in full charge of maintenance and operation of the system after purchasing the product.

11.1 Maintenance by users

11.1.1 System clean, disinfect and sterilize

⚠Warning: Turn off the instrument and pull out the power supply wire before cleaning every instrument of the system. It may cause electric shock if clean the system under power is on.

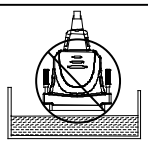
⚠Warning: There is no any water-roof device in the system. Do not splash any water or liquor into the system when cleaning or maintaining; otherwise it will cause malfunction or electric shock or malfunction.

⚠Attention:

1. **Probe without cleaning, disinfection or sterilization may become the source of contamination, so cleaning or disinfection to the probe is very necessary after every ultrasonic diagnosis.**
2. **To prevent possible infection, it is advisable to wear sterilized gloves when clean, disinfect or sterilize the ultrasonic probe.**
3. **In the process of cleaning, disinfection or sterilization, avoid probe overheat (exceeding 60℃) as it may be damaged or deformed under excessive heat.**
4. **To prevent the infection or the cross infection, the probe surface should be covered with a condom every time before diagnose the cavity.**
5. **Do not use the probe packing box to store the probe as the box may become the s of contamination.**
6. **The waterproof grade of intra-cavity probe is IPX7, immersion depth from p acoustic head to the sheath of probe handle; other probes are IPX4.**

1. Clean the probe
   (1) Wear sterilized gloves to prevent possible infection.
   (2) Clean the probe with sterile water to remove all contaminants. Do not use brush as it may damage the probe.
   (3) Dry the probe with sterilized cloth or gauze after cleaning. Do not dry the probe by heating it.
2. Disinfect the probe
   (1) Wear sterilized gloves to prevent possible infection in the process of disinfection.
   (2) Clean the probe firstly before disinfection, and then wipe the probe twice with 75% alcohol.
   (3) Clean the probe with sterile water to remove residual chemicals.
   (4) Clean the water off the probe surface with sterilized cloth or gauze. Never dry the probe by heating it.

⚠Warning:
Do not place the ultrasonic probe connector into water or disinfection, sterilization liquid, as it may cause electric shock.



3. Sterilize the probe
   (1) Wear sterilized gloves to prevent possible infection in the process of sterilization.
   (2) Clean the probe firstly before sterilization. 2%glutaraldehyde disinfectant is recommended for the probe. Immerse the sound head part of the probe (See sterilization sketch map) in liquid for more than 10 hours for sterilization.

⚠Attention:
1. Please carefully read the instructions provided by disinfectant provider about the sterilization liquid concentration and sterilization method as well as the description of the dilution method.
2. Glutaraldehyde liquid should use the activator.

   (3) Clean the probe with sterile water to thoroughly remove residual chemicals.
   (4) Clean the water off the probe surface with sterilized cloth. Never dry the probe by heating it.

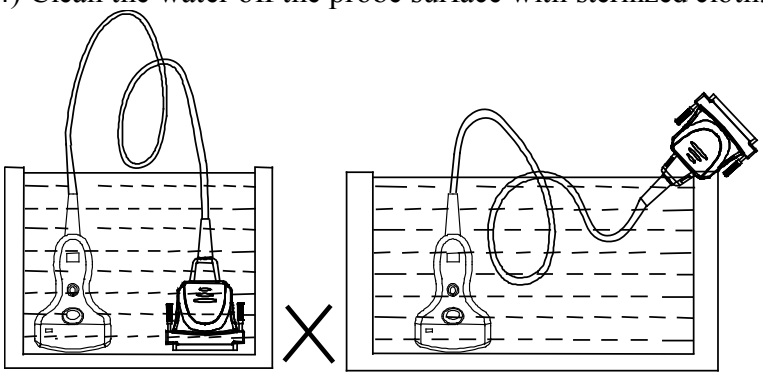


Fig. Wrong 3.5MHz probe sterilization

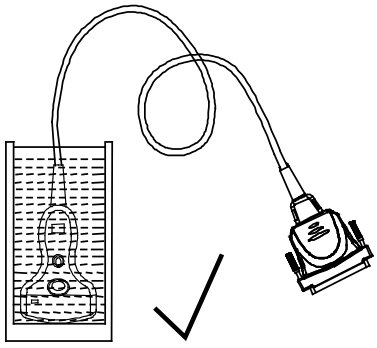


Fig. Correct 3.5MHz probe sterilization

⚠Attention:
1. **It is a normal phenomenon that color of the acoustic lens may change and color of the probe label may fade away.**
2. **To prevent the infection or the cross infection, such cleaning, disinfection and sterilization for puncture bracket and probe is very necessary before and after e puncture operation.**
3. **The sterilization times should be minimized as it may lead to degrade of the prol safety and performance.**

4. Clean the probe cable and its connector
   (1) Clean the probe cable and its connector with soft, dry cloth.
   (2) In case of die-hard blots, clean with soft cloth dipped in moderate detergent and then air-dry it.
5. Clean the liquid crystal display
   Clean the liquid crystal display with dry, soft flax. Anti-static LCD clean cloth for cleaning liquid crystal display is also applicable.

> ⚠**Attention: Do not clean the screen with hydrocarbon detergent such as alcohol or OA equipment cleaning media. These kinds of liquid may degrade the internal function of the screen.**

6. Clean the control panel and enclosure
   Clean the instrument surface with soft, dry cloth or with soft cloth dipped in moderate water cleaning media to remove the blots, and then dry the instrument with soft, dry cloth or with air.
7. Clean the video recorder
   (1) Use the soft dry cloth to wipe the video recorder.
   (2) If it is difficult to wipe away the blemish, clean with soft cloth dipped in moderate detergent and then air-dry it.

11.1.2 Use and maintenance for the charging battery

1. Only the battery provided by Kaixin Company can be used.
2. Battery is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.
3. The full charged battery can be used for 1.5~2 hours; the minimum charging time is 3 hours and up to 4 hours; over-charging or discharging will shorten the battery life.
4. The excess high or low temperature will affect the charging and discharging performance, and short the battery life and capacity.

> ⚠**Attention: Battery charger shall meet the requirements of the IEC60601-1 standard.**

> ⚠**Attention: Battery is consumable; the battery cycle-life is based on the times of charge and discharge as unit. When the use time reduced significantly compared with normal conditions, the battery should be promptly replaced.**

> ⚠**Attention: A power indicator will appear "X" and glitter continually when the electric quantity is too low. Connect the main unit to external power supply and recharge the battery, or turn off the machine to recharge.**

> ⚠**Attention: If long-term use exrernal power or do not intend to use the equipment within such a period of time, please remove the battery, to avoid over-charging or discharging the battery which will curtail battery life, or to reduce other risk.**

> ⚠**Attention: Don't throw away the exhausted battery anywhere; especially throw the fire. Please deal with it according to local statutes.**

Note: The cautions of using battery see the warning label on the battery in details.

11.2 Troubleshooting

To ensure normal operation, users are recommended to prepare a proper maintenance and regular examination plan to regularly check on product safety performance. If any abnormity occur, timely contact International Trade Dept of Kaixin for support.

If the following problems occur on starting up the machine, try to make corrections following the method in the table. If the problem remains unsolved, contact International Trade Dept of Kaixin for support.

Trouble	Correction
Power light is off and no screen display is present when starting the machine.	1. Check power supply. 2. Check power cable and connector. 3. Check power adapter.
Character and gray scale are displayed, but no ultrasonic image on the screen.	Probe is not properly connected. Turn off the power and reconnect the probe.
Intermittent stripe, snow, or far-field interference appears on screen.	1. Check power supply.(spark interference present) 2. Check environment.(source of interference around the machine, such as electric motor, ultrasonic atomizer, automobile, computer or other interference) 3. Check power plug/socket of the instrument or probe connectors. They shall be properly contacted.
Image display is not clear.	1. Adjust the total gain, near field, far field. 2. Adjust the brightness and contrast level.
Control panel malfunction	Restart the system by turning off the main unit power.

Chapter Twelve System Maintenance

⚠Warning: For optimal performance and personal safety, product service should be performed only by qualified service personnel. Customers outside China should contact their local factory-authorized distributor for service or call Tel: +86-516-87732932, 87733758 consult the International Trade Dept of Kaixin.

⚠Attention: Xuzhou KAIXIN will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable.

⚠Attention: To ensure the performance and safety of instrument, it must be checked after using 1 year. When check the instrument, please consult the International Trade Dept of Kaixin, as they need to have professional technology engineers.

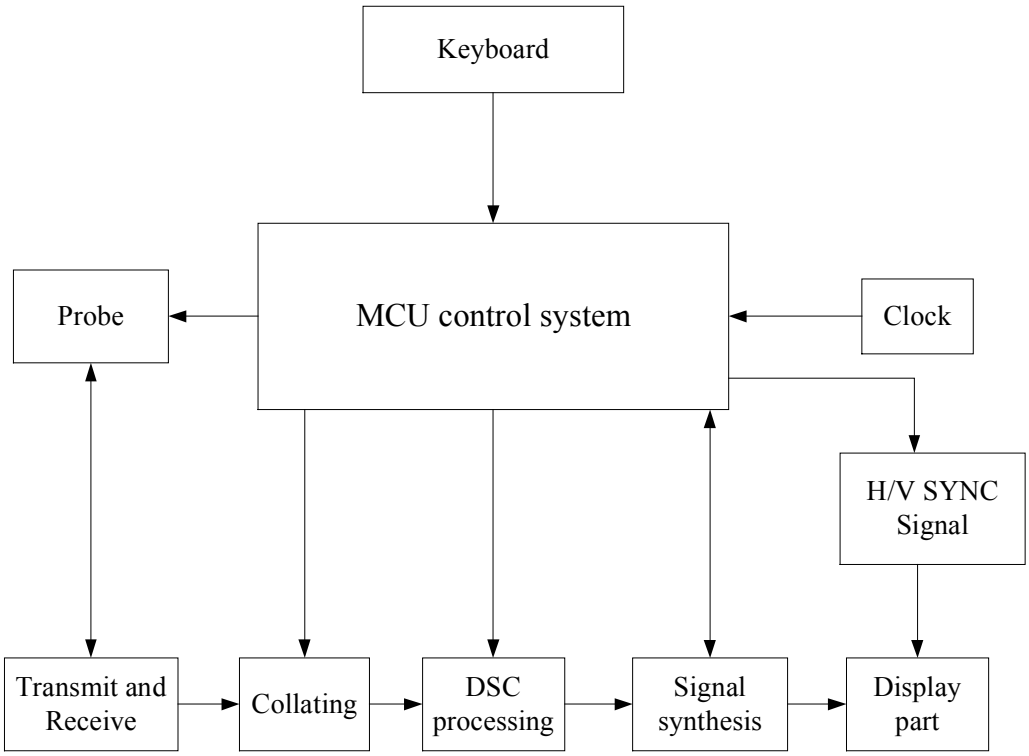
PERIODIC SAFETY CHECKS
For

12.1 Seasonal Safety Check

1. Please clean the plug of power cord at least once a year. Too much dust on plug may cause the fire.
2. The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

① Inspect the equipment and accessories for mechanical and functional damage.
② Inspect the safety relevant labels for legibility.
③ Inspect the fuse to verify compliance with rated current and breaking characteristics.
④ Verify that the device functions properly as described in the instructions for use.
⑤ Test the protection earth resistance according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: 0.1Ω.
⑥ Test the earth leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 500μA, SFC: 1000μA.
⑦ Test the enclosure leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 100μA, SFC: 500μA.
⑧ Test the patient leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: for a.c.: 100μA, for d.c.: 10μA.
⑨ Test the patient leakage current under single fault condition with mains voltage on the applied part according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: for a.c.: 500μA, for d.c.: 50μA.

12.2 The circuit theory chart of KX5100



Chapter Thirteen Accuracy of Measurement

Table 13-1 Accuracy in measurement

Parameter	Numeric range	Deviation
M-mode image time	1, 2, 3, 4, 5, 6, 7, 8s	1s:± 3 ms 2s:± 6 ms 3s:± 9 ms 4s:± 12ms 5s:± 15 ms 6s:± 18 ms 7s:± 21 ms 8s:± 24 ms

Table 13-2 Two-dimensional image measurement

Parameter	Numeric range	Deviation
Distance/depth	Max. Value 194mm	Within ± 3%; or less than 2mm when measured value is less than 40mm.
Area	Max. Value 448 cm^2	Within ± 7%; or less than 1.5 cm^2 when measured value is less than 16 cm^2.
Area (Ellipse)	Max. Value 360 cm^2	Within ± 7%; or less than 1.5 cm^2 when measured value is less than 16 cm^2.

Table 13-3 Time/motion measurement

Parameter	Numeric range	Deviation
Distance	Max. Value 194mm	Within ± 3%; or less than 2mm when measured value is less than 40mm.
Time	Max. Value 8s	Within ± 1%
Heart rate	8-252 times/s	Within ± 3%
Slope	Max.7250mm/s	Within ± 4%

Table 13-4 Volume measurement

Parameter	Numeric range	Deviation
Volume	Max. Value 999 cm^3	Within ± 10 %; or less than 7cm^3 when measured value is less than 64cm^3.

⚠**Attention: In the selected view range, the measurement can guarantee the above-listed accuracy specification. The accuracy specification is based on the system performance in the worst environment or on the real system measurement. The accuracy specs above do not include the impact imposed by sound beam error.**

Chapter Fourteen Storage and Transportation

Storage and Transportation

1. If the instrument is stored over 3 months, take out the instrument from the packing case, connect it to power supply for 4 hours, and then disconnect the power and place it in the case again following the direction indicated by arrows on the package. Store the case in the warehouse. Do not pile the case. The instrument case should have adequate space from ground, walls and ceiling of the warehouse.
2. Environment requirement:
   Ambient temperature: -20℃－55℃; Relative humidity: 30%－93% (without condensation);
   Atmospheric pressure: 700hPa-1060hPa. The warehouse should be well ventilated and free of direct sunlight and corrosive gas.
3. Shockproof measures have been taken inside the packing case to allow for transport by air, railway, land and sea. The goods shall not be exposed to poor weather conditions like rain and snow, nor shall the goods be placed upside down, bumped, knocked or over-stacked.

Chapter Fifteen Standard Compliance

The compliant standards are listed below:

93/42/EEC
EN ISO 14971
IEC 60601-1
IEC 60601-1-1
IEC 60601-2-37
IEC 60601-1-4
IEC 60601-1-2
EN 980
EN 1041
IEC 61157
EN ISO 10993-1
EN ISO 10993-5
EN ISO 10993-10

Chapter Sixteen Safety Classification

1. Classified according to electric shock protection type:
   Class I, internally powered equipment
2. Classified according to electric shock protection degree:
   Type B applied part
3. Classified according to the degree of protection against ingress of liquid:
   Main unit belong to IPX0 equipment
4. Classified according to operation safety in condition of existence of flammable anesthetic mixture with air or oxygen or nitrous oxide:
   It is neither of category AP equipment nor of category APG equipment
5. Classified according to mode of operation:
   Continuous operation equipment
6. Classified according to the protection of radio services:
   Group I Class A equipment

Chapter Seventeen Guidance and Manufacturer's Declaration

This product complies with EMC test standard EN60601-1-2

Guidance and manufacturer's declaration—electromagnetic emission

This equipment is intended for use in the electromagnetic environment specified below. Customer or user shall assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	This equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	This equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuation/flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration—electromagnetic immunity

This equipment is intended for use in the electromagnetic environment specified below. Customer or user shall assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 6 KV contact ± 8 KV air	± 6 KV contact ± 8 KV air	Floors shall be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	± 2 KV for power supply lines	± 2 KV for power supply lines	Mains power quality shall be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 KV differential mode ± 2 KV common mode	± 1 KV differential mode ± 2 KV common mode	Mains power quality shall be that of a typical commercial or hospital environment.
Power frequency magnetic field (50 Hz) IEC61000-4-8	3A/m	3A/m	Mains power quality shall be that of a typ commercial or hospi environment.

Guidance and manufacturer's declaration—electromagnetic immunity

This equipment is intended for use in the electromagnetic environment specified below. Customer or user shall assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Voltage dips short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5%U_T (>95%dip in U_T) for 0.5 cycle 40%U_T (60%dip in U_T) for 5 cycles 70%U_T (30%dip in U_T) for 25 cycles <5%U_T (>95%dip in U_T) for 5 sec	<5%U_T (>95%dip in U_T) for 0.5 cycle 40%U_T (60%dip in U_T) for 5 cycles 70%U_T (30%dip in U_T) for 25 cycles <5%U_T (>95%dip in U_T) for 5 sec	Mains power quality shall be that of a typical commercial or hospital environment. If the user of this equipment requires continued operation during power mains interruption, it is recommended that the equipment be powered from an uninterruptible power supply.
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 V_{rms} 150KHz to 80MHz 3 V/m 80MHz to 2.5GHz	1V_{rms} 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of this equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=3.5\sqrt{P}$ $d=1.17\sqrt{P}$ 80MHz to 800MHz $d=2.33\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol

Note 1: U_T is the a.c. mains voltage prior to application of the test level.
Note 2: At 80MHz and 800MHz, the higher frequency range applies.
Note 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this equipment is u exceeds the applicable RF compliance level above, the equipment should be observe verify normal operation. If abnormal performance is observed, additional measures ma necessary, such as reorienting or relocating the equipment.

b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 1V/m.

Recommended separation distance between portable and mobile RF communications equipment and this equipment

This equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and suggested distance below is based on calculation of the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	150KHz to 80MHz d=3.5√P	80MHz to 800MHz d=1.17√P	800MHz to 2.5GHz d=2.33√P
0.01	0.35	0.12	0.23
0.1	1.11	0.37	0.74
1	3.50	1.17	2.33
10	11.07	3.69	7.38
100	35.00	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Statement:

When performing common mode conducted RF disturbance test (IEC61000-4-6), trivial radiation stripes may appear on the screen when 1V disturbing voltage is added. That disturbance does not affect the diagnosis.

Appendix A1: Sound Power Output Parameter Disclosure

Pursuant to the pertinent provisions of *Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment GB 16846 -1997*, we hereby make our declaration of the relevant acoustic output parameters as follows:

Xuzhou Kaixin Electronic Instrument Co., Ltd.

Type B Full Digital Ultrasonic Diagnostic Instrument

Test Frequency: 3.5MHz

Acoustic output data for KX5100

Probe model / Mode / Parameter	Probe model:3.5C60A2 Probe No.:3.5C80/603024		
	B	**M**	**B/M**
Maximum space averaged acoustic power output, mW	25.6	43.2	23.2
Peak negative sound pressure P- Mpa	1.30	1.30	1.30
Sound intensity of output beam I_{ob}, mW/cm^2	2.77	19.81	2.51
Space peak time averaged sound intensity output I_{spta}, mW/cm^2	9.79	280.70	10.36
System settings	Focus mode: 1 section Depth:17cm Scan scope:3	Focus mode: 1 section Depth:17cm M speed:1s	Focus mode: 1 section Depth:17cm M speed:4s
Distance between transducer output end surface and integral dot for square of the maximum acoustic pressure Lp, mm	70	70	70
−6dB pulse beam width W_{pb6} (‖), mm (⊥), mm	(‖): 3.51 (⊥): 4.54	(‖): 3.98 (⊥): 5.19	(‖): 3.28 (⊥): 4.95
Pulse repetition rate prr, kHz	N.A.	4.608	64.10
Scan repetition rate srr, Hz	53.19	N.A.	32.05
Output beam size, cm^2	9.24	2.18	9.24
Arithmetic average acoustic working frequency, f_{awf}, MHz	3.05	3.05	3.06
Acoustic power-on factor APF, %	100%	100%	100%
Power-up mode	B-Mode	B-Mode	B-Mode
Acoustic initial factor AIF, %	100%	100%	100%
Initialization mode	B-Mode	B-Mode	B-Mode
Acoustic output freeze	yes	yes	yes

Appendix A2: Sound Power Output Parameter Disclosure

Pursuant to the pertinent provisions of *Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment GB 16846 -1997*, we hereby make our declaration of the relevant acoustic output parameters as follows:

Xuzhou Kaixin Electronic Instrument Co., Ltd.

Type B Full Digital Ultrasonic Diagnostic Instrument

Test Frequency: 5.0 MHz

Acoustic output data for KX5100

Probe model / Mode / Parameter	Probe model:5.0C20A3 Probe No.:5.0C6420/605003ASK		
	B	**M**	**B/M**
Maximum space averaged acoustic power output, mW	13.8	18.9	8.2
Peak negative sound pressure P-Mpa	1.66	1.60	1.66
Sound intensity of output beam I_{ob}, mW/cm^2	4.00	21.97	2.37
Space peak time averaged sound intensity output I_{spta}, mW/cm^2	14.14	246.13	10.4
System settings	Focus mode: 1 section Depth:10cm Scan scope:3	Focus mode: 1 section Depth:10cm M speed:1s	Focus mode: 1 section Depth:10cm M speed:4s
Distance between transducer output end surface and integral dot for square of the maximum acoustic pressure Lp, mm	30	30	30
－6dB pulse beam width W_{pb6} (‖), mm (⊥), mm	(‖): 2.36 (⊥): 4.00	(‖): 2.00 (⊥): 3.73	(‖): 2.00 (⊥): 3.75
Pulse repetition rate prr, kHz	N.A.	4.608	64.10
Scan repetition rate srr, Hz	78.37	N.A.	32.05
Output beam size， cm^2	3.45	0.86	3.45
Arithmetic average acoustic working frequency, f_{awf}, MHz	4.14	4.15	4.15
Acoustic power-on factor APF, %	89.75%	93.12%	89.75%
Power-up mode	B-Mode	B-Mode	B-Mode
Acoustic initial factor AIF, %	89.75%	93.12%	89.75%
Initialization mode	B-Mode	B-Mode	B-Mode
Acoustic output freeze	yes	yes	yes

Appendix A3: Sound Power Output Parameter Disclosure

Pursuant to the pertinent provisions of *Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment GB 16846 -1997*, we hereby make our declaration of the relevant acoustic output parameters as follows:

Xuzhou Kaixin Electronic Instrument Co., Ltd.

Type B Full Digital Ultrasonic Diagnostic Instrument

Test Frequency: 6.5 MHz

Acoustic output data for KX5100

Probe model / Mode / Parameter	Probe model:6.5C13A1 Probe No.:6.5C64/603001		
	B	**M**	**B/M**
Maximum space averaged acoustic power output, mW	2.1	3.5	2.3
Peak negative sound pressure P- Mpa	1.15	1.15	1.15
Sound intensity of output beam I_{ob}, mW/cm^2	0.76	5.07	0.83
Space peak time averaged sound intensity output I_{spta}, mW/cm^2	3.79	57.77	3.69
System settings	Focus mode: 1 section Depth:10cm Scan scope:3	Focus mode: 1 section Depth:10cm M speed:4s	Focus mode: 1 section Depth:10cm M speed:4s
Distance between transducer output end surface and integral dot for square of the maximum acoustic pressure Lp, mm	23	23	23
－6dB pulse beam width W_{pb6} (‖), mm (⊥), mm	(‖): 1.99 (⊥): 3.96	(‖): 2.65 (⊥): 3.29	(‖): 1.99 (⊥): 3.95
Pulse repetition rate prr, kHz	N.A.	4.608	64.10
Scan repetition rate srr, Hz	71.42	N.A	32.05
Output beam size， cm^2	2.75	0.69	2.75
Arithmetic average acoustic working frequency, f_{awf}, MHz	5.96	5.84	6.43
Acoustic power-on factor APF, %	100%	100%	100%
Power-up mode	B-Mode	B-Mode	B-Mode
Acoustic initial factor AIF, %	100%	100%	100%
Initialization mode	B-Mode	B-Mode	B-Mode
Acoustic output freeze	yes	yes	yes

Appendix A4: Sound Power Output Parameter Disclosure

Pursuant to the pertinent provisions of *Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment GB 16846 -1997*, we hereby make our declaration of the relevant acoustic output parameters as follows:

Xuzhou Kaixin Electronic Instrument Co., Ltd.

Type B Full Digital Ultrasonic Diagnostic Instrument

Test Frequency: 7.5 MHz

Acoustic output data for KX5100

Probe model / Mode / Parameter	Probe model:7.5L40A3 Probe No:7.5L40A3/612002		
	B	**M**	**B/M**
Maximum space averaged acoustic power output, mW	7.8	9.3	7.3
Peak negative sound pressure P- Mpa	2.69	2.69	2.69
Sound intensity of output beam I_{ob}, mW/cm^2	1.72	8.23	1.61
Space peak time averaged sound intensity output I_{spta}, mW/cm^2	23.89	386.04	15.39
System settings	Focus mode: 1 section Depth:10cm Scan scope:3	Focus mode: 1 section Depth:10cm M speed:1s	Focus mode: 1 section Depth:10cm M speed:4s
Distance between transducer output end surface and integral dot for square of the maximum acoustic pressure Lp, mm	30	30	30
−6dB pulse beam width W_{pb6} (‖), mm (⊥), mm	(‖): 1.24 (⊥): 1.73	(‖): 1.24 (⊥): 1.55	(‖): 1.21 (⊥): 1.75
Pulse repetition rate prr, kHz	N.A	4.608	64.10
Scan repetition rate srr, Hz	71.42	N.A	32.05
Output beam size, cm^2	4.51	1.13	4.51
Arithmetic average acoustic working frequency, f_{awf}, MHz	4.69	4.69	4.68
Acoustic power-on factor APF, %	100%	100%	100%
Power-up mode	B-Mode	B-Mode	B-Mode
Acoustic initial factor AIF, %	100%	100%	100%
Initialization mode	B-Mode	B-Mode	B-Mode
Acoustic output freeze	yes	yes	yes

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Information contained in this manual is subject to change without further notice.